

k954506

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA**I. General Information**

A. Submitted By: MedTrak International, Inc.
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B. Device Trade Name: emOx™
Common Name: Emergency Oxygen Generator
Classification Name: Portable Oxygen Generator

C. Predicate Device: Model 415 Oxygen Canister
(Jet Research, Inc. - k780020)

D. Device Description:

The emOx™ device is a lightweight, portable device that produces oxygen of greater than 99% purity by a chemical reaction. The evolved oxygen bubbles pass through a water-filled chamber to humidify the gas on its way to the patient via flexible, ribbed tubing and an open adult or pediatric face mask.

The device, other than the face mask, does not come into contact with the patient. The mask is a currently legally marketed adult or pediatric mask. The oxygen container is constructed of polypropylene. Therefore, the biocompatibility of the materials used is without significance.

E. Intended Use:

The emOx™ device by MedTrak is intended to generate 99% pure oxygen for emergency first aid administration.

F. Device Comparison:

The MedTrak emOx™ Emergency Oxygen Generator is substantially equivalent to various other currently legally marketed devices, including the Model 415 Oxygen Canister by Jet Research Center, Inc. Each of these devices generates a minimum of 60 liters of oxygen of greater than 99% purity by chemical

reaction, which can be delivered to the patient at 4.0 L/min. or greater mean flow rates.

II. Testing

A. Non-clinical Tests:

Testing was performed by independent test laboratories for the following:

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|------------------------------|-------------------------------------|
| 1. Purity of oxygen produced | > 99% pure |
| 2. Contaminants | No detectable CO or CO ₂ |
| 3. Stability | No fire or explosion hazard |
| 4. Decomposition products | Non-toxic |
| 5. Mean Flow rate | 4.6 L/min |

B. Clinical Tests:

No clinical tests were performed.

C. Test Conclusions:

MedTrak's emOx™ device meets product specifications and requirements of the Food and Drug Administration for classification as a Portable Oxygen Generator.